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Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket Nos. 2002N-0276 and 2002N-0278

Dear Sirs:

These comments are filed in response to both the Registration and the Prior Notice Dockets on behalf of the American Free Trade Association (AFTA). AFTA is a trade association of wholesalers, retailers, importers and distributors of a wide range of consumer goods, including the food products governed by the BioTerrorism Preparedness Act of 2002 (the "Act").

Comments Submitted to Registration Docket Number 2002N-0276

A. The costs of the existing facility registration regulations

The FDA is presently seeking comments related to the costs and burdens placed upon foreign facilities having to engage a U.S. agent in order to be properly registered with the FDA and the impact of those burdens upon U.S. businesses relying upon these facilities to supply the articles being distributed within the U.S. marketplace. The Agency presumably intends to compare the effect of these costs on the total cost of imported food articles available to U.S. consumers after full enforcement and implementation of the FDA's BioTerrorism Regulations (the "BTA Regulations"). However, such a limited scope of inquiry would inappropriately ignore other significant economic harm caused by the BTA Regulations, such as the fact that the Regulations will raise consumer prices and lessen competition as products become unavailable. The costs of the registration requirements are not merely those placed upon foreign facilities that now must engage a U.S. Agent, but also include the costs to warehouse operators, truckers, brokers, forwarders, carriers and bankers, all of whom will lose the business of importers unable to ship, transport, store or distribute even the safest of food products as a result of the BTA

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Regulations, and to consumers who will be forced to pay for the increased regulation without gaining any noticeably safer domestic food supply.

B. Two Problems – Selective Registration and Foreign Facility NonCompliance

Because the Regulations only require registration of facilities manufacturing food for consumption in the United States, the FDA has left it exclusively to the discretion of the owner of the manufacturing facility itself[1] as to whether or not it should – or is required to --- register with the FDA. This type of selective regulation presents at least two separate problems.

The first is that certain food manufacturers will select which of their several facilities to register with the FDA, thereby intentionally choosing which facilities to *not* register with the FDA – without having to disclose to anyone whether or why such a distinction has been made. In this way, that manufacturer is able to ensure that the food only from selected, registered facilities will enter the United States --- even if there is no difference between the food manufactured in registered facilities and the food manufactured in others. This blatantly contradicts the protections afforded under U.S. law to international traders who are able to freely distribute genuine products to U.S. consumers in order to provide the competition upon which the national marketplace thrives.

The second problem posed by this limited registration process is that certain facility owners overseas may simply not register their facilities because they may not know that their products are, in fact, distributed within the U.S. market. Again, because of the competition currently available in the U.S. marketplace, products from all over the world that are safe, unadulterated and fully compliant with U.S. law may be freely distributed here by any reputable businessman – that is, until the FDA rulemaking that hinged such distribution upon registration with the Agency by particular individuals even though they may have no reason to undertake such an effort or expense and/or may choose to intentionally prevent these otherwise lawful and commercially critical activities.

C. The costs of selective registration, manufacture and distribution

Turning then to the first problem noted above (i.e, selective facility registration), the FDA is reminded that there is no law in the United States that permits a party to prohibit importation or reimportation of genuine, safe products that are identical in all material respects to other products distributed in the domestic market. In fact, even for those products that are safe and unadulterated but which may in fact be somehow materially and physically different from those

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[1] For purposes of these comments, "owner" is intended to include also the operator or agent in charge of the subject facility and "manufacture" is intended to encompass all those processing activities requiring facility registration under the Regulations.

nationally distributed by the original manufacturer itself, the Bureau of Customs and Border Enforcement (CBP) still permits (under its Lever-Rule Regulations in 19 CFR 133.23), importation of that product so long as it is clearly labeled to alert consumers to such differences. So long as the article poses no threat to a U.S. consumer, no property right is infringed and the article is not a counterfeit version of the product, no U.S. laws and regulations impede the free distribution and resale of lawful goods.

The FDA regulations have administratively, and with no expression of congressional support or mandate, overturned such dictums by permitting a food manufacturer to select which food it will allow to be distributed in the U.S. marketplace and, consequently, at what prices and to whom - with no required guarantee of food safety or quality. The FDA regulations would effectively accomplish this because international and domestic food manufacturers alike can choose which of their facilities to register with the FDA (selective registration), which food products will be manufactured at those facilities (selective manufacture) and which businesses will be allowed to import or distribute those items to American consumers (selective disclosure). This is an unacceptable breach of the protections against misuse of property rights U.S. consumers have a right to depend upon and, moreover, provides those same consumers with no reciprocal benefit of increased food security. The cost to the American consumer of the FDA's registration rulemaking may not be as obvious as the expense of engaging a U.S. Agent to a foreign food facility but may, in fact, be even more overwhelming as the national marketplace becomes a select channel of trade for the chosen few.

D. The cost of imposing registration requirements upon unrelated and unknown foreign facilities

Foreign food facilities may, without concern, lose control of their products once they enter the open marketplace. These items may change hands between various wholesalers, brokers and traders and, although never altered as to condition or quality, may arrive at a U.S. port without the original food manufacturer having any knowledge or care about such ultimate destination. Such facility owners, agents or operators have no cause to register with the FDA; the cost of engaging a U.S. Agent and the perceived difficulties in registering with a federal governmental agency would overcome any thought of possible benefit even if such thought were to occur in the first place.

Any responsibility for doing business in the United States would be a responsibility thought to be appropriately charged to the U.S. distributor of the products, should one ultimately exist, especially since the foreign facility has already profited as much as it ever will from any related business transaction. Since it has already earned its reward from the production and initial sale of the food article, there is no reason for the foreign facility to, on its own, undertake the responsibility of registering itself with the FDA or, in fact, with any other "foreign" government. Once the article leaves the facility, the place where it is ultimately sold or

consumed is of no consequence to the original foreign manufacturing facility, although it is of great consequence to the ultimate exporter and U.S. importer – neither of whom may have any direct relationship to the original food manufacturer and neither of whom has, under the FDA's interim final rulemaking, any method of importing these completely safe food products into the United States because the original food manufacturer may be unknown, unavailable and, in most cases, outside the jurisdiction of the United States federal government.

As a result, the cost of the existing registration requirement is not merely the expense of engaging a U.S. Agent by a foreign facility choosing to continue doing business with the United States or the measurable losses suffered by domestic small businesses when an existing foreign supplier elects to no longer provide products to U.S. distributors because of the BTA Regulations. The costs that must be considered by the FDA as a part of its analysis must also include the lost business incurred by the food exporter and the U.S. importer with no relationship to the foreign manufacturing facility who are prevented from "registering" that facility with the FDA – even if they are willing to voluntarily disclose such source. Because the FDA regulations provide no incentive for registration of all global food facilities and no ability for anyone other than the owner of that facility to officially register with the Agency, not only are these traders' ongoing lawful businesses threatened and potentially thousands of jobs lost, but consumers are deprived of product variety and the competition created by such product diversity.

Comments Submitted to Prior Notice Docket 2002N-0278

The FDA's reopened comment period focuses on the processes the FDA should follow were it to provide preferential treatment of Prior Notices submitted by participants in certain CBP-related programs and related queries related to the wisdom in encouraging a flexible approach to Prior Notice submission. AFTA fully supports the FDA's providing preference to certain importers who are able to satisfy Agency requirements as to the safety, security and integrity of their entire supply and distribution chains. Similarly, AFTA fully supports and urges the FDA to adopt a flexible approach not only in connection with the submission of the Prior Notice but also in connection with Agency review of the information contained therein. In this way, many of the concerns noted above in connection with the costs of the registration requirement on U.S. businesses could very well be mitigated if not eliminated entirely.

A. Verification of Qualified Importer

The FDA has focused primarily on importers participating in CBP's C-TPAT and FAST programs for likely consideration for preferential processing of the Prior Notice submission. However, in its request for comments, FDA has also indicated that it is not completely satisfied with the criteria used to qualify in these particular CBP programs to automatically grant such benefits without at least some degree of additional confirmation of supply chain security measures by the FDA itself. In a sense, the FDA appears to be exploring its own type of low-risk

importer program, adopting membership in the CBP programs as the first qualifying measure that must be met. The members of AFTA would welcome the opportunity to become qualified FDA low-risk importers (FDA-LRI).

However, AFTA urges the FDA to publish clear guidelines setting forth the criteria for qualifying as a FDA-LRI, the methods for accomplishing such a designation and the benefits provided to those meeting such stringent standards. For example, it would be unreasonable to limit FDA-LRIs to importers of a particular type, size or reputation. Similarly, it would be unreasonable to withhold qualification as a FDA-LRI if a particular third party participant in the supply chain, uncontrolled by the importer, resists U.S. federal agency inspection – qualification must, instead, depend upon the representations and certifications as to policies and procedures undertaken by the importer itself to verify supplier and product safety and security. While publication of FDA-LRI members may be desirable and in fact a benefit of participating in the program, confidentiality of all information provided to the Agency leading to the determination of such status must be guaranteed --- as is presently the case for all food facility registrations. And, finally, importers gaining the privilege of FDA-LRI certification must be assured that Prior Notices submitted with sufficient information for the FDA to verify product safety and lawfulness will be accepted, guaranteed in effect by the qualifications and reputation of the FDA-LRI itself.

Moreover, while FDA is drafting and finalizing its FDA-LRI program, it must utilize discretion in the enforcement of its Prior Notice regulations. For all of the reasons set forth herein and in earlier comments submitted to the FDA by AFTA and others, there are a host of reasons why the Prior Notice may be incomplete at the time of submission yet still contain enough information for the FDA to verify product safety and compliance with U.S. law and regulations. Accordingly, the FDA should recognize the value of facilitating the continued businesses of low risk importers and should adopt the type of flexible approach to Prior Notice submission and review that will permit continued global trade in safe food products, even while the Agency works toward implementation of its own low-risk importer certification program. As AFTA's members and other importers work toward acquiring the status of a FDA-LRI, they must not be put out of business because the FDA insists on strict and immediate full enforcement of the Regulations.

B. Flexible Approach for Prior Notice Submission and Review

The overwhelming concern of AFTA's members and other legitimate importers of genuine food products supplied through a food broker, wholesaler or other source not directly related to the original food manufacturer is that the FDA will so strictly enforce its Prior Notice regulations that those Prior Notices submitted without a manufacturing facility's registration number will be automatically and absolutely refused - without regard as to the reason the number is not being made available to the importer and even if the submission fully identifies the

manufacturer so that the FDA would clearly be able to verify registration status. If the FDA implements regulations that enable only the manufacturer-controlled selective facility registration processes described above, then it must provide an alternative means for the importer to satisfy the FDA that the product may be lawfully imported and distributed into the domestic marketplace. To hold otherwise – to not adopt flexible border enforcement procedures that would encourage inspection of documents or similar interaction between port inspectors and importers - would unacceptably deny equal access to the U.S. market, favoring those with the greatest market power and monopolistic policies.

The FDA should exercise flexibility in its review of the Prior Notice so that lawful, safe, unadulterated food products are not automatically refused entry, to the detriment of the American consumer, merely for lack of a particular facility's registration number on the Prior Notice. The U.S. Congress placed the burden upon the FDA to ensure that a facility's owner, operator or agent in charge complies with the registration requirements established under the Act and while it is reasonable for the FDA to request that importers assist them in this task by asking for facility registration numbers on Prior Notice submissions, the Agency must not condition lawful entry on the provision of this number that may, for a variety of reasons, be unavailable to the importer.

The FDA port personnel should be encouraged to work with importers to verify the lawfulness of the products being imported even if the Prior Notice does not contain a manufacturing facility's confidential registration number. Because the imported food article must be from a registered facility, the FDA should work with the importer to determine, through review of certificates of origin or other similar documentation, whether or not this condition has been met. Importantly, the failure to register a facility is not a violation committed by the importer – it is a Prohibited Act committed by the owner of that facility. Accordingly, all efforts should be undertaken to spare the punishment that may be inappropriately imposed against the unrelated importer, especially if the FDA is able to otherwise meet its obligation to ensure that products entering the U.S. marketplace are imported only from registered facilities.

C. Particular Issue: U.S. Goods Returned

Of great import to the following discussion is the fact that Section 305(a)(1)(2) of the Act specifically requires that a facility registrant advise the FDA of all facilities at which it conducts business. Accordingly, Congress specifically eliminated the ability of a facility with multiple locations being able to effectively "hide" certain of those facilities from FDA oversight or inclusion in its food facility database.

The FDA has confirmed that the Prior Notice and registration requirements apply even in connection with domestically manufactured products that are reimported back into the United States by third party importers. The concerns regarding unavailability of manufacturing facility registration numbers are magnified in this scenario because of the selective registration

procedures permitted by the FDA that will allow U.S. manufacturers to choose which of perhaps several domestic manufacturing plants will be registered with the FDA and places no obligation upon that manufacturer to disclose the distinction. Nevertheless, because of the requirements of Section 305(a)(1)(2), the FDA must possess internal records documenting the location of all domestic manufacturing facilities because a registrant of any one such plant must identify all others. Because Congress has charged the FDA with the responsibility of ensuring that goods entering the U.S. are only from registered facilities, it is reasonable to expect that the FDA will access those records to verify the registration status of a product's manufacturing facility. And, should the FDA determine that the particular manufacturing facility at which a domestically produced product was manufactured is not duly registered with the Agency, the FDA has no alternative but to charge the owner of that facility with the commission of a Prohibited Act under the Federal Food Drug and Cosmetic Act.

The failure to register a facility manufacturing food for consumption in the U.S. is a Prohibited Act committed by the owner of that facility – not by the importer. In other words, the Regulations specifically provide: (1) that products may only be imported from registered facilities; (2) that all facilities manufacturing food for consumption in the U.S. must be registered with the FDA; and (3) that the only parties able to so register a manufacturing facility is that facility's owner, operator or agent in charge. Moreover, neither the Regulations nor the underlying legislation prohibit the purchase of products from an unregistered facility and the FDA has confirmed this fact in its guidance documents published on the FDA website. Therefore, if an international trader (1) lawfully purchases domestically manufactured products outside of the United States, (2) wishes to bring those products into the United States for consumption and (3) the FDA (through a search of its records that must necessarily include information on all such domestic manufacturing facilities) learns that the particular domestic facility that produced those products is not registered with the Agency, the violator of the FDA regulations would be the owner of that facility – not the international businessman who had no means of verifying facility registration prior to lawful purchase.

In the case where a domestically manufactured product arrives at a U.S. port from an apparently unregistered manufacturing facility, the FDA's sole remedy is to demand registration of the facility by its owner, operator or agent in charge. This is true because both the Act and the Interim Final Regulation prohibit importation of goods from an unregistered *foreign* facility, but make no mention whatsoever of automatic refusal of products manufactured or produced in an unregistered *domestic* facility. The owner of the domestic manufacturing facility that produced the goods that are now intended for consumption in the United States is required under law to register that facility with the FDA; there is no provision under law or regulation that excuses such registration merely because the importer is a party not known to or authorized by the manufacturer itself.

Admittedly, while the foregoing paragraph accurately represents the current state of U.S. law and the obligations of the relevant parties to the transaction being described, it also presents the FDA with particular difficulties and burdens that may lead the Agency into conflicts it has no desire to become a party to. For this reason, especially in connection with domestically manufactured goods for which the FDA has sufficient information on hand to verify the safety and lawfulness of the arriving article intended for consumption within the U.S. marketplace, it would be reasonable, just and more than appropriate for the FDA to adopt a flexible approach encouraging acceptance of a Prior Notice even without the manufacturing facility's registration number.

CONCLUSION

While AFTA continues to appreciate the opportunities afforded to its members to become a part of the FDA's rulemaking process, it is clear that these Regulations are not yet in a form suitable for full enforcement. There are problems with both the registration and the Prior Notice regulations – if these regulations are enforced in their present form, lawful trade not targeted by the statute will be eliminated and U.S. consumers will be deprived of competitive and distinctive food products because it is, quite frankly, easier to deny legitimate imports than it is to draft regulations more fairly apportioning responsibility under the Act.

Proposed mechanisms such as a FDA Low Risk Importer program should be pursued, food manufacturers should be required to disclose the registration status of all food facilities and domestic manufacturers should be held fully liable in the event a manufacturing facility is not duly registered with the FDA. In addition, AFTA is aware of other comments received by the FDA bringing to the Agency's attention the fact that the Prior Notice systems are not yet fully operational, are still experiencing significant periods during which they are completely inaccessible and that more clarification is needed in connection with responsibility for timely transmission of the Prior Notice. Finally, because the FDA, as promised, is continuing its efforts to integrate the Agency's systems with those of CBP in order to ease the burdens of global commerce, these efforts must not be compromised by a rush to enforce these particular regulations to the detriment of international traders bound by the requirements of both agencies' rules.

The FDA is encouraged to expeditiously publish notice that it intends to continue outreach and delay enforcement of the BTA Regulations so that the business community may have a greater opportunity for education, training and continued dialog with the Agency. With the Regulations still in need of modification to address these significant commercial issues, it is respectfully hoped that the FDA will, while it continues to review comments received and hone internal processes, exercise substantial enforcement discretion at the border so that issues such as a lack of a manufacturing facility's registration number on an otherwise-compliant Prior Notice

transmission will not exclusively serve as the basis to refuse importation of safe and unadulterated food products.

AFTA continues to encourage agency review of these regulations. AFTA would be pleased to facilitate such discussions and would suggest that participants from Congress, CBP and the Administration be included - together with representatives from the trade and the FDA - to further discuss shared costs, impact and responsibilities. Upon your review of these comments, we look forward to continuing our work together in this regard and trust that you will contact the undersigned or Lauren Perez of this office directly to more thoroughly discuss the issues raised in this communication.

Respectfully submitted
American Free Trade Association

By:_____
Gilbert Lee Sandler
General Counsel

cc: Lauren Perez
AFTA Board of Directors and FDA Committee Members
Dr. Lester Crawford, FDA Commissioner
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